Together, improving life

Rev 1: September 2018
FSN Ref: 0000000.11152019.001-R FSCA Ref: 0000000.11152019.001-R

Date: 18-NOV-2019

Urgent Field Safety Notice
GORE® DrySeal Flex Introducer Sheath

For Attention of*: Healthcare Professionals and/or Hospital Inventory Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
Claire van den Nieuwenhof EMEA Regulatory Affairs W. L. Gore & Associates B.V. Ringbaan Oost 152-a 5013 CE Tilburg The Netherlands cvandenn@wlgore.com T +31 135 074 728 M +31 6 29 45 07 26

Rev 1: September 2018

FSN Ref: 0000000.11152019.001-R FSCA Ref: 0000000.11152019.001-R

Urgent Field Safety Notice (FSN)
GORE® DrySeal Flex Introducer Sheath
Mislabelled 16Fr Introducer Sheaths Labelled as 14Fr (3 lots)

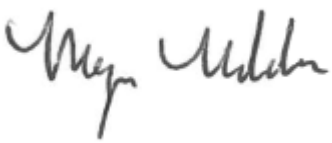
1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Sterile Introducer Sheath
1.	2. Commercial name(s)
	GORE® DrySeal Flex Introducer Sheath
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not Applicable
1.	4. Primary clinical purpose of device(s)*
	The GORE® DrySeal Flex Introducer Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.
1.	5. Device Model/Catalogue/part number(s)*
	DSF1433
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	See "Acknowledgement and Return Form" for lot number(s) identified as sold or in consignment at your location.
1.	8. Associated devices
	Within context of the FSCA – not applicable

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	An incorrect part number on a certificate of conformance sent to Gore resulted in Gore labelling 576 devices with an incorrect product size. All the affected units are labelled as 14Fr but the physical devices are actually 16Fr.
2.	2. Hazard giving rise to the FSCA*
	Hazardous Situation: Sheath being labelled as smaller than it is in actuality when used for the necessary clinical situation. The hub of the sheath and dilator are correctly labelled. Per the IFU, adequate vessel access is required to introduce the sheath into the vasculature. Careful evaluation of vessel size, anatomy, tortuosity, and disease state (including calcification, plaque, and thrombus) is required to ensure successful sheath introduction and subsequent withdrawal. If vessel is not adequate for access, major bleeding, vessel damage,

	or serious injury to the patient, including death, may result. Hazards are only applicable to the patient, there are no known hazards to the user. The harm associated with this hazard is increased procedural time, injury to, or hemorrhage from, access vessels (e.g., dissection, rupture, perforation, tear, etc.). This is due to the device outer diameter (OD) being larger than anticipated by 0.8 mm. This may result in access vessel damage including dissection, rupture, perforation and tear.
2.	3. Probability of problem arising
	The probability of the hazardous situation arising is very likely. The hazardous situation of the sheaths being larger than expected is true for every device included in this evaluation. While the sheath itself has the correct size marked on the hub and dilator, both the inner and outer packaging is mislabelled.
2.	4. Predicted risk to patient/users
	Low - The hazardous situation in question is not likely to cause adverse health consequences
2.	5. Further information to help characterise the problem
	Not applicable
2.	6. Background on Issue
	In a review of historical documentation received from Gore's contract manufacturer, Gore associates noted that three batches of 16Fr GORE® DrySeal Flex Introducer Sheaths were incorrectly identified as 14Fr, which resulted in 576 units of 16Fr size devices being boxed and labelled labelled as 14Fr devices and released for distribution. Based on the Supplier investigation, there is no indication that product beyond the scope of this FSN is affected. Corrective Actions are being pursued to prevent a recurrence.
2.	7. Other information relevant to FSCA
	None

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None

	All product identified as sold to consignee or in consignment at consignee's location shall be verified as previously used, or if in inventory, shall be returned to Gore. Any returned units shall be replaced. Please follow instructions on the attached "Acknowledgement and Return Form."	
3.	2. By when should the action be completed?	Identify and quarantine as soon as possible Return acknowledgement form and affected devices as soon as possible but no later than 29-NOV-2019.
3.	3. Particular considerations for:	Not applicable
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Product is to be removed from inventory and returned to the manufacturer for disposition. Corrective Actions are being pursued internally.	
3	6. By when should the action be completed?	Not applicable
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Competent Authorities of all affected countries have been informed of this communication.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	 Megan Madden Aortic Accessories Product Specialist

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Rev 1: September 2018

FSN Ref: 0000000.11152019.001-R FSCA Ref: 0000000.11152019.001-R

	Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Rev 1: September 2018

FSN Ref: 0000000.11152019.001-R FSCA Ref: 0000000.11152019.001-R

Customer Acknowledgement and Return Form

Field Safety Corrective Action (FSCA): 0000000.11152019.001-R / MD175033

Affected Item(s):

Lot/Serial Number	Catalogue Number	Location	Inventory Status (check only one)	
			Used	In Stock
	DSF1433			

Please inspect all inventory for the above lot/serial numbers. Return any identified product for replacement. Please return this form by 29-NOV-2019, even if items are no longer in inventory.

Availability of Affected Item Confirmed: ☐ Yes ☐ No

Indicate above for each lot/serial number if Item was used or is still in Customer inventory. If not in inventory, but not used – provide explanation:

Retrieval of Affected Item: (If affected item is in Customer Inventory)

☐ Not Required, Item Used

☐ Affected Item Removed from Customer's Location

Replacement Order: (Replace only if an item is retrieved and returned)

☐ Not Required, Item Used

☐ Replacement Item delivered to customer

☐ Replacement Item order placed with Customer Service – Order No.: _____

Return of Affected Item:

☐ Not Required, Item Used, Return Paperwork only (see below)

☐ Affected Item Removed from Customer's Location:

- Ship Device(s) to: **W. L. Gore & Associates**
  Attn: Rutger Muntjewerf
  Dr. Paul Janssenweg 150
  5026 RH Tilburg
  The Netherlands

  Contact Gore Customer Service for return information

Rev 1: September 2018

FSN Ref: 0000000.11152019.001-R FSCA Ref: 0000000.11152019.001-R

Person Responsible for Completing Information:

Print Name: _____

Signature: _____

Date: _____

Return Paperwork:

- Email Paperwork to: **bfilleru@wlgore.com**
- Or include paperwork with returned devices

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

==========

Fore Gore Field Sales Associates Only:

Field Sales Associate: _____

Customer Communication Completed on: _____